IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Robert C. Brunham
Appl'n. No.	:	09/857,305
Filed	:	October 3, 2001
Title	:	TWO-STEP IMMUNIZATION PROCEDURE AGAINST CHLAMYDIA INFECTION
Grp./A.U.	:	1645
Examiner	:	Khatol S. Shahnan-Shah
Docket No.	:	1038-1153 MIS:jb
Date	:	October 6, 2003

Via Facsimile **(703) 305-3014**

Mail Stop Amendment
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
U.S.A.

AMENDMENT

Dear Sir:

This Commission is submitted in respect to the Office Action of September 5, 2003.

The Examiner required an election of a single invention among three groups of claims. The applicants hereby elect the claim of Group II, namely claims 19 to 28, drawn to an attenuated bacterium. This election is made without prejudice to applicants right to file one or more divisional or continuation applications directed to the non-elected invention.

The election is made with traverse. The Examiner indicates that

"The special technical feature testing Groups I to III appears to be immunological activity of a major outer membrane protein (MOMP) of a strain of *Chlamydia*. However, Agabian et al teach immunological activity of the major outer membrane protein (MOMP) of a strain of *Chlamydia*.

> "Therefore, the technical feature listing the invention of Groups I to II does not constitute a special technical feature as defined by PCT Rules 13.2, as it doe not define a contribution over the prior art."

It is submitted that the Examiner is incorrect. It is true that Agabian et al disclose that MOMP is immunogenic. However, the reference shows only that *in vitro* recombinantly produced MOMP protein is immunogenic.

Applicants claims all involve the use of an attenuated bacteria harbouring a nucleic acid molecule encoding at least one immunoprotection-inducing *Chlamydia* protein or fragment thereof which generates a *Chlamydia* protein specific immune response, specifically MOMP. Claims 1 to 18 are directed to a two step immunization procedure and claims 29 to 40 are directed to one step immunization procedure using said attenuated bacteria while claims 19 to 28 are directed to bacteria itself.

The special feature linking the groups of the claims, therefore, is the attenuated bacteria and its use in DNA immunization. As is clear from the disclosure on page 8, lines 7 to 15, the transfected DNA (i.e. the nucleic acid molecule encoding MOMP) is <u>not</u> expressed in the bacterial vector and hence the attenuated bacterium could not be used to produce *in vitro* MOMP, as in Agabian et al. The expression of the DNA is effected when the bacterial vector has released the DNA into the appropriate host cells. After uptake of the bacterial vector by the host cells, the auxotrophic bacteria dies after a few rounds of division and the plasmid DNA then is released into the cytoplasm of the infected host cells and the encoded gene expressed in the host cell.

Accordingly, it is submitted that the restriction requirement is improper and that all claims should be examined in this application. Nevertheless, as noted above, applicants have elected the claims of Group II.

In addition, the Examiner required an election of species, indicating that, with respect to the claims of Group II, an election was required between the

Chlamydia species of claims 21 and 22. The applicants hereby elect the species of claim 22, namely *C. trachomatis*. Claims 19, 20 and 23 to 29 are generic thereto

The species election is made without prejudice to the applicants right, up-on the allowance of a generic claim, to consideration of claims to additional species which are written in dependent form or otherwise include the limitations of an allowed claim.

Respectfully submitted

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DATE: October 06, 2003

Application No.: 09/857,305 **Our Ref:** 1038-1153 MIS:jb

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USPTO Commissioner of Patents **Examiner: Khatol S. Shahnan-Shah** **Art Unit : 1645**	(703) 305-3014	(703) 308-3896

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Invention: **TWO-STEP IMMUNIZATION PROCEDURE AGAINST CHLAMYDIA INFECTION**

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